



## **Recommendation 71-7**

### **Rulemaking on a Record by the Food and Drug Administration**

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(Adopted December 7, 1971)

The Federal Food, Drug and Cosmetic Act requires the Food and Drug Administration (FDA) to hold a formal evidentiary hearing in connection with promulgation of certain types of rules of general applicability. Detailed findings of fact based solely on the record must accompany the regulations, and such findings are subject to judicial review on a substantial evidence test. The general consensus of observers of the FDA is that in the past this procedure, often described as "rulemaking on a record," has worked poorly. The basic problem is that the statutory provisions require procedures which are ill-adapted to the promulgation of general rules of broad applicability. An extensive study of the desirability of "rulemaking on a record" procedures in FDA and elsewhere is underway; the recommendations contained in the present report, however, are directed toward improving the performance of FDA, given the present, and probably unwise, statutory mandate to that agency.

The FDA, in its conduct of "rulemaking on a record" proceedings, has not adopted procedures followed by many other agencies to facilitate large multiparty proceedings. As a consequence, these proceedings have been unnecessarily lengthy and burdensome to all parties. The following recommendation is directed toward (1) encouraging the increased use of written testimony, (2) seeking to improve the delineation of factual areas of controversy in advance of the hearing, (3) providing for greater access to information about the agency's case in advance of the hearing, and (4) altering the agency's approach toward ex parte contacts and separation of functions.

#### **Recommendation**

In conducting rulemaking proceedings pursuant to section 701(e) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 371 (1970), the Food and Drug Administration of the Department of Health, Education, and Welfare should adopt the following procedures:



## ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

### **A. Informal Opinions**

During the pendency of a section 701(e) proceeding, the FDA should encourage requests addressed to it for informal written opinions as to the applicability of the proposed regulations to specific situations so that potential participants can determine whether it is necessary for them to participate further in the proceeding. The agency should respond to such requests to the extent it has views on the subject. Informal opinions issued pursuant to this recommendation should be made publicly available as required by the Freedom of Information Act, and the agency should consider publishing the most important such opinions in the Federal Register.

### **B. Delineation of Issues in the Notice of Hearing**

The FDA should consider the "statement of issues" in the Notice of Hearing as the first step in isolating the questions to be considered at the formal hearing. To this end, it should—

(a) Amend its regulations to state that the "statement of issues" is not jurisdictional, but may be augmented or revised at the prehearing conference or hearing by order of the hearing examiner.

(b) State explicitly in the notice that while the agency is required by statute to support every aspect of the stayed regulations by substantial evidence, the issues to be considered at the formal hearing will generally be limited to the issues as augmented or revised.

(c) Formulate the "statement of issues" to the extent practicable in terms of areas of disagreement rather than in the ultimate language of the statute itself.

### **C. The Prehearing Conference**

1. The FDA should make more effective use of the prehearing conference to isolate the areas of disagreement and narrow the scope of the hearing. To this end—

(a) The hearing examiner should normally require each participant (including the agency), at an early stage of the prehearing conference, to distribute to the other participants a written statement summarizing the testimony and proof to be adduced by witnesses called by the participant. The statement should include the names of prospective witnesses, the nature of the testimony of each witness, and a list of documentary evidence to be introduced.

Documentary evidence referred to in written statements should be made available by each participant for inspection and copying by any other participant. After the distribution of written



## ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

statements, the prehearing conference should seek to establish the precise areas of disagreement. The hearing examiner may direct that discussion of issues be conducted off-the-record, but all statements as to areas of disagreement should be reduced to writing or be the subject of a verbatim transcript approved by the participants.

(b) The hearing examiner may require written objections by participants to the areas of disagreement as stated by the Government in the notice of hearing, and may receive oral or written argument in connection with such objections.

(c) The hearing examiner should describe in writing the areas of disagreement, and in the absence of surprise, cross-examination at the hearing should be limited to the areas of disagreement, as defined at the prehearing conference.

2. The prehearing conference should (i) identify the witnesses to be cross-examined, (ii) determine whether the examination is to extend beyond the witnesses' direct testimony, and if so, define the scope of the examination, (iii) determine whether restrictions should be imposed on cross-examination, (iv) identify documents for admission into evidence, (v) establish hearing dates, deadlines for distributing written direct testimony, and the sequence in which witnesses will be produced for cross-examination, (vi) establish the routine use of standard scientific treatises, and (vii) establish the manner in which the qualifications of expert witnesses are determined. In the absence of surprise or unexpected developments, procedures and time periods established at the prehearing conference should be adhered to at the hearing.

3. If the proceeding is a complex one and the hearing is to be held in stages, the foregoing procedures should be applicable only to the first stage, and should be repeated for subsequent stages. Discretion as to the scheduling of such further stages should be vested in the hearing examiner.

### **D. The Conduct of the Hearing**

1. The hearing should be conducted so as to encourage submissions of evidence in written form and discourage excessive oral examination or cross-examination. To this end the FDA should adopt regulations specifying that direct testimony should normally be submitted in written form, though where appropriate, the witness may be permitted by the hearing examiner to supplement his written direct by a short oral direct presentation. Generally, all participants should be required to distribute their written direct testimony before any witness is produced for cross-examination, and the distribution of the written direct testimony by the



## ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

proponent of the proposed regulation should precede the distribution of written direct testimony by other participants.

2. The hearing examiner should exercise substantial authority over cross-examination in order to eliminate irrelevant or cumulative testimony and to expedite the hearing. Cross-examination which does not relate to the areas of disagreement as defined in the prehearing conference should be excluded as irrelevant, though the hearing examiner should have authority to modify the description of the areas of disagreement at the hearing where appropriate to prevent prejudice to any participant. Examination relevant to any matter at issue should be permitted even though not raised by the witness's direct testimony if (i) within the knowledge, competence or expertise of the witness, and (ii) at the prehearing conference the participant desiring to cross-examine the witness specifies the areas to be covered by the cross-examination and shows that the proposed examination will produce testimony which cannot conveniently be introduced by direct testimony. The participant producing such witness may be permitted to cross-examine the witness as to testimony beyond the scope of his direct testimony.

3. If several participants with common interests desire to cross-examine a witness, the hearing examiner should encourage the participants to select a lead attorney or attorneys to conduct the cross-examination. In the absence of a showing of prejudice, participants with common interests should be grouped by the hearing examiner, and participants in a group should not be permitted to cross-examine witnesses called by other members of the group.

### **E. Obtaining Information and Documents from FDA**

1. The FDA should routinely make available to any participant prior statements of a witness produced by the agency which are in its files and which relate to the subject matter of the expected testimony if (i) the statement was made before the person agreed to become a witness for the agency, or (ii) the statement was published by the witness. "Statements" should include written statements signed or adopted by a witness or a recording or transcription of an oral statement made by the witness but should not include investigative reports, internal agency memoranda or the like which the agency would not be required to produce under the following paragraph.

2. The FDA should routinely make available upon request all unprivileged factual information in its files which relates to the subject matter of the hearing. Documents which contain such information should usually be made available upon request, whether or not the



## ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

production of such documents may be required under the Freedom of Information Act. In considering such requests the agency should proceed on the assumption that disclosure is presumptively required in every case. Refusal to disclose should be based only on strong reasons, for example that the information represents trade secrets, or possible violations of the Act by non-participants, or internal memoranda the disclosure of which would seriously hinder the effective operation of the agency. The exceptions referred to in the preceding sentence should be construed more narrowly than the similar language in the Freedom of Information Act has been construed by the agency in the past. If the agency refuses to provide requested information or documents, it should to the maximum extent feasible provide summaries or descriptions or excerpts of information appearing in such documents.

3. Requests for information from FDA files for purposes of the hearing should be accepted after the notice of hearing is issued and generally should cease when the hearing begins. The hearing examiner should be vested with authority, subject to interlocutory review by the agency to the extent permitted by its rules, to rule on questions relating to production of information, documents and prior statements of witnesses, and to issue appropriate orders to protect the interest of any participant or other person.

### **F. Ex Parte Communications**

1. The FDA should amend section 2.104 of its regulations, 21 CFR § 2.104, to clarify that disclosure of ex parte communications under that section is required if—

(a) The communication is with or to the Commissioner, Deputy Commissioner or presiding hearing examiner;

(b) The communication occurs after the publication of the notice of hearing;

(c) The communication is (i) from a non-agency participant, the attorney appearing on behalf of the agency at the hearing, or a member of the FDA staff assisting such attorney at the hearing, and is not served on or communicated to all participants, or (ii) is from a person not a participant and not an agency employee; and

(d) The communication relates to the substantive issues involved in the proceeding as described in the notice of hearing or to the desirability of adopting regulations which have been stayed and are the subject of the hearing.



## ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

2. Section 2.104 should be further amended to require that disclosure of an ex parte communication should include a statement or summary of the information imparted or contentions advanced in the communication.

3. The agency should also amend its regulations to give an opportunity to participants to introduce evidence or argument to rebut facts or contentions made in any ex parte communications, disclosure of which is required by section 2.104.

4. The Commissioner, Deputy Commissioner and presiding hearing examiner should refrain from soliciting ex parte communications after the notice of hearing is issued.

### **G. Separation of Functions**

1. The Department of Health, Education, and Welfare should adopt organizational changes within the office of General Counsel so that the attorneys who prepare and conduct a section 701 (e) hearing do not participate in the preparation of the tentative or final order. Legal assistance to the Commissioner of the FDA and the Secretary of HEW on such matters should continue to be provided by the Office of the General Counsel even though hearing attorneys are subject to oversight and control by the General Counsel and his subordinates.

2. Members of the staff of the agency who assist the agency attorney at the hearing should not participate in the preparation of the tentative or final order.

### **H. Participation by Citizen Groups**

The FDA should urge lay participants not represented by counsel to file statements or participate in the proposal stage of the proceeding rather than to act as a formal participant in the hearing. Such persons who desire to have their views made part of the formal record should be permitted to testify orally and in narrative fashion on the record at the formal hearing without being "called" by one or more of the participants. This recommendation is not applicable to persons, groups or agencies who are represented by counsel.

### **I. Denial of Hearings by FDA**

No purpose is served in holding evidentiary hearings when the only issues in dispute involve purely legal disputes or will not affect the ultimate outcome of the proceeding. However, the agency should grant public hearings where the objections set forth in the request for hearing, if true, would invalidate the proposed regulation. Hearings should be granted when a prima facie showing has been made that an objection which meets this standard does exist. If



## ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

the issues involved in such hearings are not those which are suitable for development at a formal trial-type of hearing, the agency should employ procedural devices to limit the scope of the hearing, produce most evidence and testimony in written form, and expeditiously create a formal record on which the correctness of the agency's factual conclusions may be tested.

### **Citations:**

\_\_ FR \_\_\_\_ (2012)

2 ACUS 42

**Note:** This recommendation was not published previously in the Federal Register.